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Contents

Preface

0.1 Copyright

0.2 Attention

This operation manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards.

For any modifications and upgrades, the informations in this document are subject to change without notice.

This operation manual includes special documents which are under protection of copyright law.

All rights reserved. Without written announcement from our company, the user manual should not be transferred, copied or translated into other languages.

Our company assumes no responsibility for incidental or consequential damage in connection with the furnishings, performance or use of this material.

0.3 Manufacturer's Responsibility

The manufacturer only consider itself responsibility for any effects on safety, reliability and performance of the equipment if:

Assembly operations, extensions, readjustments, modifications or reparation are carried out by persons authorized by manufacturer, and the electrical installation of the relevant room compiles with national standard, and the document is used in accordance with the instruction for use.

If necessary, we can provide necessary circuit diagram and other documents to help qualified technicians to maintain and repair the device.

0.4 Warranty

The unit can not be repaired by users. All services must be done by the engineers approved by manufacturer. We warrant that each product is

free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty.

0.5 Explanation

 : The label refers to follow operation manual.

NOTE: Provides useful informations of a function or a procedure.

0.6 Warnings

⚠WARNING⚠: The label advises against certain action or situation that could result in personal injury or death.

⚠WARNING⚠: The label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

⚠WARNING⚠: This device is not intended for treatment.The intended use is for inspecting of FHR. If the FHR result is distrustful, please use other methods such as stethoscope to verify immediately.

Section 1 Safety Guidance and Symbols

1.1 General Safety

Before using the device, carefully examine the fetal heart doppler(hereinafter called device) and the accessaries to ensure the main unit and accessaries do not have any visible damage evidence that may affect patient safety and device performance.

The device is used for fetal heart rate test, and not intended for any treatment. If the test FHR result is useless, please try to test by other clinical test methods.

Installment, adjustment, maintance and reparation can be carried out only by qualified or authorized personnels from manufacturer.

It is forbiddened to copy or translate any part of the content of the manual to other languages without getting written permission from manufacturer.

Please observe the WARNING, CAUTION and NOTE to avoid possible injury.

⚠WARNING⚠: The device uses very low power ultrasound doppler. It is confirmed by design calculation, laboratory test, clinical test and clinical application the device doppler energy is safe for fetus, pregnant women and other personnel. Even so, it is not appropriate to use the device continuously or with long term.

⚠WARNING⚠: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

NOTE：Before using the device, please read this manual carefully and assure to be familiar with the controls, displays, features and operating techniques.

1.2 Warnings

⚠WARNING⚠: This device is not explosion-proof and can not be used in the presence of flammable anaesthetics equipment.

⚠WARNING⚠: Do not throw battery into fire as this may explode and cause danger.

⚠WARNING⚠: Do not attempt to recharge normal dry-cell battery, which may leak and cause fire or even explosion.

⚠WARNING⚠: Do not touch signal input or output connector and the patient simultaneously to avoid device damage.

⚠WARNING⚠: Accessory and equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards.

⚠WARNING⚠: The battery must be taken out from the battery compartment if the device will not be used for a long time.

⚠WARNING⚠: The operator does not contact patient when changing battery and opening battery cover.

⚠WARNING⚠: The device is a tool to aid the FHR inspection and should not be used for normal fetal monitoring.

⚠WARNING⚠: Replacing battery shall only be done outside the patient environment (1.5m away from the patient) by persons from manufacturer or persons authorized by manufacturer.

⚠WARNING⚠: Please use the specialized probe from manufacturer.

⚠WARNING⚠: Do not pull the line of probe longer than 2 meters, or else the probe may break away from the connector of the device.

⚠WARNING⚠: The device is designed for continuous operation and is ordinary. Do not immerse in any liquid (i.e. not drip or splash-proof).

⚠WARNING⚠: Keep the device clean. Avoid vibration.

⚠WARNING⚠: Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.

⚠WARNING⚠: The device is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. because of electromagnetic interference.

⚠WARNING⚠: The user must check that the equipment does not have visible damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.

⚠WARNING⚠: The device can not be used when some equipments are used, such as high frequency electrical generator, microwave oven and mobile phone.

⚠WARNING⚠: Do not use the device in the presence of flammable anesthetic mixture with oxygen or other flammable agents.

⚠WARNING⚠: The device is designed for interval operation with short time.

⚠WARNING⚠: Please stop using the device to deal with properly if the device construction is not integrated,such as the battery cover is lost.

⚠WARNING⚠: The device is feasible for relatives such as operator, responsible organization and environmental restriction, which does not need special skills, training and knowledge.

⚠WARNING⚠: This operation manual is written at a level without special education, training and other needs of individual for whom they are

intended. For using in hospital and clinic, the operator needs to have relative qualification certificate such as nurse certificate. For using at home, when the test data are used to diagnose, it should be analysed by specialized medical working personnels.

⚠WARNING⚠: This minimum qualifications of service personnel is to be familiar with our device operation and service technique.

⚠WARNING⚠: This minimum qualifications of service personnel is to be familiar with our device operation and service technique.

⚠WARNING⚠: For the women to be sensitive to gel, please change gel to water or oil.

⚠WARNING⚠: If using unmatched earphone,it will affect sound effect.

⚠WARNING⚠: After packing, the machine can be sent by air,sea, land. When transporting, the machine can not be stored in the open.

⚠WARNING⚠: The following safety checks should be performed once every half an year or as specified in the institution's test and inspection protocol by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

1. Inspect the equipment for mechanical and functional damage.
2. Inspect the safety relevant labels for legibility.
3. Verify that the device functions properly as described in the instructions for use.
4. Test the patient leakage current according to IEC 60601-1: limits less than 100uA (B).

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

1.3 Cautions

⚠CAUTION⚠: The battery must be properly disposed according to local regulation after use.

⚠CAUTION⚠: The battery must be taken out from the battery compartment if the device will not be used for a long time.

⚠CAUTION⚠: The device shall only be used when the battery cover is closed.

⚠CAUTION⚠: Battery must be stored in cool and dry place.

⚠CAUTION⚠: If use rechargeable battery, to insure capability and life, please fully charge batteries before first use, normally, batteries must be continuously charged over 4 hours or charged according to the guidance displayed on the battery.

⚠CAUTION⚠: Please do not set anode and cathode of the battery wrongly.

⚠CAUTION⚠: The informations in this manual are subject to modify without notice.

The device usage life is 6 years, after which please treat according to relative regulations.

⚠CAUTION⚠: Do not use strong solvent (for example, acetone) and abrasion material to clean the device.

⚠CAUTION⚠: Do not allow any liquid to enter the device, and do not immerse any parts of the device into any liquids.

⚠CAUTION⚠: Please choose the accessories and expendable authorized by manufacturer.

⚠CAUTION⚠: Never try to sterilize the probe or equipment by low temperature steam or other methods.

1.4 Symbols

All the symbols are described as follows.

Symbol	Explanation
	Type BF
	Attention, refer to the accompanying documents
	Headphone socket
ON/OFF	Power ON/OFF
	Battery symbol
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
P/N	Part number
S/N	Serial number
	Date of manufacture
	Manufacturer
EC REP	Authorized representative in the European community

Section 2 Introduction

2.1 Intended Use

The device is used to detect the fetal heart rate. The device can be used by health care professionals including nurses, midwives, specialized technicians in hospital, clinic, community and home. The 2MHz and 3MHz probe are used for detection of fetal heart rate. The 5MHz and 8MHz probes are used for detection of veins and arteries blood flow for assisting to detect periphery vascular disease.

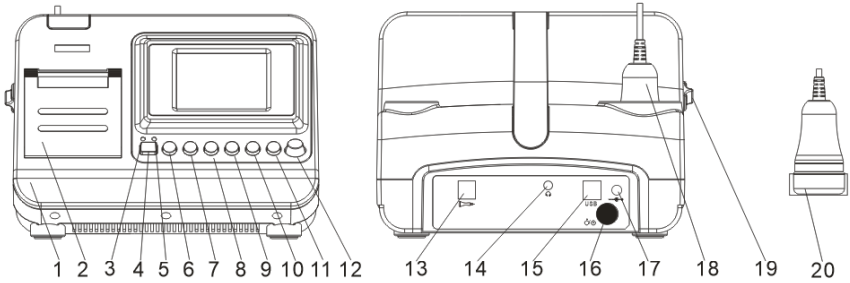
2.2 Product Features

Function	SONOTRAX PRO
Display	Colour
Build-in speaker	Yes
Volume adjustable	Yes
Audio recording	Yes
Ni-Mh battery	Yes
Battery indicator	Yes
Audio alarm	Yes
Light alarm	Yes
FHR curve	Yes
Probe detect	Yes
Various work modes	Yes
Various display modes	Yes
Earphone	Optional
PC software	Optional
Trolley	Optional
2.0MHz probe	Yes
2.5MHz probe	Optional
3.0MHz probe	Optional
Printing system	Optional

Section 3 Appearance

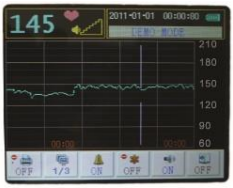
3.1 Appearance

1) Main Body
2) Printer Cover
3) AC Light
4) Power On/Off
5) Power Light
6) Printing Key
7) Alarm On/Off Key
8) Freezing Key
9) Display
interface
switching
10) Playback Key
11) Zoom key
12) Encoder
Switch
13) Probe connection port
14) Earphone Port
15) USB Port
16) Power Switch
17) DC Port
18) Probe
19) Printer Key
20) Water-proof Parts



3.2 Display

3.2.1 the display type is as follows



Curve

Parameter and Digit

Large Digit

3.2.2 The Menu Displays are as Follows

3.3 Controlling Keys

In 3.1 main unit configuration, there are nine keys as follows.

3.3.1 Power ON/OFF

When power switch is on, press key once to turn on the device. When the device is working, press key for 3 seconds to turn off the device.

3.3.2 Printing Key

When the device equipped with printing function and install printer, the print key will be used, otherwise the print key is reserved key. Put the paper in print storehouse , the device will check it automatically, and then can start to open and close the print function. Print key to start printing .and press key again to stop printing.

The printing speed can be set in menu: 1cm/min, 2cm/min, 3cm/min.

3.3.3 Freezing Key

Press key to freeze FHR on LCD will be freezed. This will keep till another measurement starting, changing the mode or pressing this key again.

3.3.4 Display interface switching

Press key to Display interface switching.

3.3.5 Playback Key

Press  key to Playback of stored data.

3.3.6 Zoom key

Press  key to Zoom the current curve display interface.

3.3.7 Encoder Switch

When working, rotating the encoder switch  is to adjust volume. Press the encoder switch to enter into menu setting , rotate to required menu and press the encoder switch again, rotate the encoder switch to select the parameters and press the encoder switch to confirm. Rotate to select menu and press again to exit the menu setting.

3.3.8 Power Switch

Turn on the back power switch  , the front switch is feasible,on and off.Turn off the back switch, the front switch is infeasible, and the battery is recharged.

3.4 Indicating Lights

There are two lights with code (3) and (5) in main unit configuration.

3.4.1 Power Indicator Light

When turning on the device, the light is bright all the time.

3.4.2 Charge Indicator Light

When charging, it is orange colour. After finishing charging, it is green.

3.5 Work Modes

For any work modes, the FHR is automatically displayed on LCD. There are these work modes as follows.

3.5.1 Real-time Mode

In this mode, the heart symbol on LCD will flash, and real-time FHR is displayed on LCD simultaneously. You can record or stop recording by pressing key once.

3.5.2 Averaged Mode

This mode is used to get more stable heart rate values. The LCD displays the flashing heart symbol when displaying FHR. The FHR value is averaged and displayed during the setting time.

3.5.3 Manual Mode

This mode is used for FHR is not enough to display for doppler but can be audible. Press Power key once, start to count. The LCD displays the flashing heart shape symbol and "---".Press Power key again on the tenth count(after 9 beat internals). The device automatically calculates the derived FHR averaged over the 10 beat periods and display the FHR value. This rate value will keep till another measurement starts or the mode is changed.

3.5.4 Demo Mode

This mode is to display the data which is stored into device in advance.

3.6 Display Modes

There are three display modes as follows.

3.6.1 Curve Mode

Under this display mode, The device displays FHR curve and relative parameters.

3.6.2 Large FHR Digit Mode

Under this display mode, the device displays FHR value and relative parameters.

3.6.3 Large FHR Digit & Info Mode

Under this display mode, the device display FHR value, main work parameters and other informations.

3.7 Parameters Explanations

Sub-menu	Parameter	Explanation	Optional Value	Default Value
FHR setup	FHR volume	FHR volume	0-7	7
	Color	FHR color	ORANGE,GREEN,CYAN,PURPLE, YELLOW,WHITE	GREEN
	Print speed	Print speed	1, 2, 3cm/min	3cm/min
	Print time	Automatic print time	00-60s，00 is unlimited time	00
Alarm setup	Alarm	Alarm ON or OFF	ON,OFF	ON
	Upper limit	Alarm upper limit	60-210bpm	160bpm
	Lower limit	Alarm lower limit	60-210bpm	120bpm
	Delay time	Alarm delay time	5-20S	10
Factory set	Factory set	Factory default set	YES, NO	NO
Display mode	Only curve	Display curve and other informations	/	YES
	Only number	Display FHR number and informations	/	/
	Number &info	Display FHR, parameters,etc	/	/
Time setup	Year	Year	00-99	10
	Month	Month	1-12	01
	Day	Day	1-31	01
	Hour	Hour	00-23	12
	Minute	Minute	00-59	04
Work mode	Real time mode	Real time mode	/	YES
	Average mode	Average mode	/	/
	Manual mode	Manual mode	/	/
	Demo mode	Demo mode	ON, OFF	OFF
System set	Language	Language	ENGLISH, CHINESE	ENGLISH
	Touch panel adjustment	Touch panel adjustment	/	/

Section 4 Basic Operation

4.1 Preparing to Use

Be carefully check if the device has any damnification and if the accessaries are integrated. If so, please stop using the device and contact manufacturer or local distributor.

Keep the package for possible future transportation and storage.

Be carefully take out the probe from the probe slot at the side of the main unit. Please pay attention not to pull the probe forcibly when operating.

4.2 Using Battery

4.2.1 Taking out Battery

Unscrew the screw and take away the battery cover and take out the battery.

4.2.2 Placing the Battery

Insert the plug of battery into the battery socket and put the battery into the compartment with the wire inward.

4.2.3 Closing the Battery Compartment

Put the battery cover, screw the screw.

4.3 Operating Probes

4.3.1 Taking out and Inspecting the Probe

Before using the device, take out and inspect the probe carefully.

4.3.2 Replacing Probe

The probe is changeable. Before doing it, please turn off the device.

Press the spring plate of crystal head, pull out the plug of the probe from its socket, then connect the probe you need to the socket.

4.4 Turning on the Device

Turn on by pressing the power key once, the working indicator light is bright and the equipment can start to work.

4.5 Setting Parameter and Working Operation

Press the encoder switch to enter into menu setting , rotate to required menu and press the encoder switch again, rotate the encoder switch to select the parameters and press the encoder switch to confirm. Rotate to select menu and press again to exit the menu setting.

The setting parameters are automatically saved.

When working, press key to freeze the display on screen.

When working, press Encoder Switch to increase or reduce the FHR volume.

When working, press alarm key to turn or turn off the alarm voice.

Press print key to start or stop printing.

4.6 Assembling Paper

Press the sliding key at the side of device, open the paper cassete, take out the paper shaft, assemble the paper on the shaft, place the shaft with paper into the paper cassete, and close the paper casset cover.

The recording paper should be thermal recording paper with 50mm width and without grid.

4.7 Storing and Playing back

Press key to Playback of stored data.by rotating encoder switch, the storage data can be played back with displaying FHR curve and time mark of 2 minutes length for every picture.

4.8 Turn off the Device

When the device is power on and being work state, press the  key again for 3 seconds, the device is power off and the working indicator light is off.

After ending test, press back power switch to turn off the power.

NOTE: The device will automatically turn off with 3 minutes if it is not used.

Section 5 Inspecting and Recording

5.1 Inspecting FHR

5.1.1 Gel Usage

Daub ultrasonic gel on the probe faceplate to decrease noise and boost up test result.

5.1.2 Finding the Position of Fetus

Firstly, please feel the fetal position by hand. Place the working faceplate on abdomen with feasible tight contact. Adjust the probe position to obtain an optimum audio signal. Usually, the heart position of the fetus with small gestational age is on the 1/3 of the line from the umbilicus to symphysis pubis, and with increasing of the gestational age the position will shift upward and deviate to the left or right slightly.

NOTE: Do not compress probe too tightly on abdomen surface to avoid to weaken signal and affect the auscultation result.

NOTE: When searching for the fetal heartbeat, do not pull the probe on the abdominal surface to avoid the noise.

NOTE: Do not put the probe on the position where there is strong Placental Blood Sound(PBS) or strong.

5.1.3 FHR Inspecting

Finish setting mode and parameters, press power On/Off key to start work, press power On/Off key again to stop working.

NOTE: Do not measure FHR unless audible and identifiable fetal sound has been heard, usually it needs about 5 seconds.

NOTE: The normal value of the fetal heart rate is 120-160bpm. 100-120bpm and 160-180bpm are the critical values which should be paid some attention to. And lower than 100bpm and more than 180bpm are danger values which should be paid more attention to.

5.1.4 Adjusting Volume

When device is working, you can adjust volume by rotating encoder switch.

5.1.5 Cleaning Work

After finishing using the device, please turn off the equipment in time and wipe the gel on the probe and skin, put the probe into the probe slot.

5.2 Recording，Re-playing and Burning

The fetal sound rate signal can be transferred to personal computer and recorder by its sound corder.The sound files can be re-played, burnt into CD disk or sent to others by e-mail.

Section 6 Cleaning and Disinfecting

6.1 Cleaning

Before cleaning the device, switch off and take out the battery from main unit.

Keep the outside surface of the device clean and free of dust and dirt, clean exterior surface with a dry, soft cloth. If necessary, clean the chassis with a soft cloth soaked in a solution of soap, or water and wipe dry with a clean cloth immediately.

Wipe the probe with soft cloth to remove any remaining ultrasound gel. Clean with soap and water only.

NOTE: Wipe the surface of probe with 70% ethanol, self-air dry, or clean with a clean, dry cloth.

6.2 Disinfecting

Clean the equipment case, probe, etc. as above, and then wipe the probe with an alcohol impregnated wipe (70% ethanol).

Wipe the probe with a clean, dry cloth to remove any remaining moisture.

NOTE: Never try to sterilize the probe or equipment by low temperature steam or other methods.

Section 7 Maintance and Troubleshooting

7.1 Maintance

The device is precision equipment, and the probe acoustic surface is frangible, you need to handle the device especially probe with enough care.

Gel and dirty dunghill must be wiped from the probe after using. These precautions will prolong the life of the unit and keep the examination precision.

Before using, the user must check that the equipment does not have visible evidence of damage that may affect patient safety or device capability. The recommended inspection interval is once per week. If damage is evident, reparation is recommended before use.

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.

The accuracy of FHR is controlled by the device and can not be adjusted by user. If the FHR result is distrustful, please use other method such as stethoscope to verify immediately or contact local distributor or manufacturer to get help.

There are some optional probes. The probes can be replaced by users.

7.2 Troubleshooting

When using, if it appears following problems, please treat by following instruction. If fail to treat, please contact local distributor or manufacturer.

Problem	Main Reasons	Solutions
Weak Sound	• Voice volume is too low • Battery volume is too low	• Charge the battery or change battery • Inspect the device • Contact dealer or

	• Without sufficient gel.	manufacturer.
Weak Sound	• Voice volume is too low • Battery volume is too low • Without sufficient gel.	• Adjust higher voice volume • Change or charge the batteries • Add sufficient gel on probe inspecting surface.
High Noise	• Probe is too near from the main unit • Disturbance from the outside signal • Power is low.	• Keep the probe feasible from main unit • Be away from the outside signals • Change or charge the battery.
Low Sensitivity	• Position is incorrect • Without or insufficient gel.	• Keep the probe at right position • Daub sufficient gel.

Section 8 Warranty and After-sale Service

8.1 Warranty

This warranty is limited to repair any part or whole unit upon examination to prove they are within warranty period and range.If the product does not function during the warranty period,we will repair or replace it free of charge.

Limit of warranty:

1) Trouble resulting from misuse, negligence, accidents or transportation.
2) Opening, modification or repair by unauthorized persons from manufacturer.
3) Replacement or remove serial number lable or label.

8.2 After-sale Service

If you have any questions of use, maintance, technical specifications or malfunction of device, please contact local distributor or service department.

Section 9 Product Specifications

Model		Sonotrax Pro
Power		Ni-Mh Battery/16.8V 1800 mAh
Output Power		≤ 20W
Display		3.2”
Range		60 ~ 240 bpm
Resolution		1bpm
Accuracy		±1 bpm
Probe	Nominal Frequency	2.0 MHz
	Working Frequency	2.0MHz±10%
	P-	<1MPa
	Iob	<20mW/cm^2
	Ispta	<100mW/cm^2
	Ultrasonic Output Intensity	Isata<10mW/cm^2
	Effective Radiating Area of Transducer	208mm^2
Recommended Coubling Medium	Stimulation to skin	No
	Total Germ Quantity	<1000units/g
	Dung Escharichia Coli, Pseudomonas Aeruginosa, Staphylococcus Aureus	No
	Acoustic Velocity	1520-1620m/s
	Acoustic impendance	1.5 -1.7x10^{6}Pa.s/m
	Acoustic Attenuation	<0.05dB/(cm.MHz)
	Viscosity	>15Pa.S
	PH Value	5.5-8
Safety Feature	Anti-Electroshock Type	Externally powered equipment.
	Anti-electroshock Degree	Type BF equipment
	Harmful Liquid Proof Degree	IPX1，Ordinary equipment
	Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases
EMC		Group I Class B
Safety Standard		IEC60601-1:2012 IEC 60601-1-2:2014 IEC61266:1994 IEC 60601-2-37:2015
Material Group		I
Pollution Degree		II
Operating Altitude		<2000m
Overvoltage Class		I
Dimension		225 x 220 x 162 mm
Weight		1.6 kg
Operating	Temperature	5 ~ 35℃

	Humidity	<80%
	Atmosphere	86 ~ 106 kPa
Storage	Temperature	-10 ~ 55
	Humidity	≤95%
	Atmosphere	50 ~ 106 kPa

Section 10 Appendix

10.1 Overall Sensitivity

Distance for the probe face	200mm	100mm	75mm	50mm
Nominal acoustic working frequency	2.0MHz	2.0MHz	2.0MHz	2.0MHz
Doppler frequency	332Hz	332Hz	332Hz	332Hz
Target Velocity	4.8cm/s	4.8cm/s	4.8cm/s	4.8cm/s
A(d): Target reflection loss	44.5dB	44.5dB	44.5dB	44.5dB
B：two-way attenuation over the acoustic pathway	41.8dB	44dB	47dB	47dB
C: Signal-to-noise Ratio	Vs: 712 mV Vn: 304 mV C=7.3dB	Vs: 716mV Vn: 304 mV C=7.3dB	Vs: 720mV Vn: 305 mV C=7.4dB	Vs: 723 mV Vn: 306 mV C=7.5dB
S: Overall Sensitivity	S=93.6dB	S=97.5dB	S=102.3dB	S=102dB
Supplementary information: --				

10.2 Guidance and Declaration of EMC

Guidance and manufacturer's declaration – electromagnetic emissions The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The [EQUIPMENT or SYSTEM] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	**Compliance level**	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for Power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5% UT for 0.5 cycle 40% UT for 5 cycles 70% UT for 25 cycles <5% UT for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [EQUIPMENT or SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [EQUIPMENT or SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between Portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]			
The [EQUIPMENT or SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [EQUIPMENT or SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [EQUIPMENT or SYSTEM] as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.16\sqrt{P}$	80 MHz to 800 MHz $d = 1.16\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{p}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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